Client information note

Assessment and Certification – ISO 22716:2007

Overview

The assessment process for ISO 22716 follows the same general process as for ISO 9001 Quality Management System assessment and certification.

If your company does not hold ISO 9001 certification with Lloyd's Register Quality Assurance (LRQA), please request a copy of the Client information note for ISO 9001 for more details.

You do not have to have ISO 9001 certification to seek certification against ISO 22716.

Where required, we can combine assessment work for ISO 22716 and ISO 9001 for new or existing approvals. Where an LRQA ISO 9001 certification is already in place, we assess the requirements of ISO 22716 by adding more time to planned surveillance or renewal visits.

Process

The assessment process normally includes two visits to your site(s) before we can recommend approval.

We call these two visits:

- Stage 1 (document review and planning visit). The Stage 1 visit will be for a minimum of one day.
- Stage 2 (initial assessment)

Following certification we will carry out surveillance visits every 6 or 12 months. Where you have more than one site certified, we will visit each site at least annually, including any offices responsible for managing regulatory requirements.

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Reporting

ISO 22716 is a set of Good Manufacturing Practices (GMP) Guidelines and as such it does not contain specific, mandatory requirements. The Guidelines are written in the form of *recommendations.*

In many cases these are quite specific and local authorities may interpret these as requirements that must be met. Our assessors will be aware of local interpretations applied to the ISO 22716 GMP and will apply these accordingly

Where clients do not meet a recommendation (or recommendations) in ISO 22716, and where there is no acceptable justification for this, we will record this as a 'Major Non-conformity' in the assessment visit reports.

Where one or more Major Non-conformities are identified, we will not be able to issue certification until appropriate corrective action has been demonstrated.

More details on reporting, grading and managing non-conformities are available in the ISO 9001 Client Information Note.

Sampling:

It is important to remember that even though a problem may not have been identified in the area of activity, it does not necessarily mean that there are no problems. As assessment work is based on sampling techniques, statistically there is always a possibility that issues will not be identified during an assessment.

Confidentiality:

We will not pass on any of the information we gather about your organisation (including the contents of reports) to any other person or organisation without your permission.

Further information:

To find out more about how LRQA can help you to increase performance and reduce risk, please visit our website www.LRQA.com. From here, you can also visit one of our country specific websites to find out about LRQA in your country.